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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,132	10/29/2001	Donald E. Bobo JR.	CVG-5637	2468
7590 06/02/2005			EXAMINER	
Debra D. Condino Edwards Lifesciences LLC Law Department One Edwards Way Irvine, CA 92614			SHAY, DAVID M	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,132	BOBO	
	Examiner	Art Unit	
	david shay	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 6, 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 30, and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-35 are indefinite because claim 32 recites the steps of “sealably engaging the distal portion of the medicament delivery catheter to the tissue surface” and forming a sealed opening in the tissue surface”; and subsequently recites the step of delivering medicament through the sealed opening in tissue surface so as to prevent medicament washout”. However, the final step is in the form of “step plus function”; and as such precludes the recitation of sufficient structure, material, or acts for achieving the specified function, the preceding two steps being sufficient acts to achieve the function. Thus it is unclear whether the claim is intended to recite step plus function, or the steps necessary to perform the function. It is further noted that claims 33 and 34, as well as claims 29 and 30, with respect to the fourth step in claim 28, recite further sufficient acts, while claim 35 recites no clear step.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mueller ('528).

See figures 9-11 and column 13, line 24 to column 14, line 29.

Claims 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al in combination with Cox et al and Ryan et al. Jenkins et al teaches a method as claimed (see column 1, line 20 to column 2, line 54). Cox et al teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when the procedure is performed on a beating heart. Jenkins et al teach the desirability of providing drugs to the site of ablation in a cardiac chamber. It would have been obvious to wedge the probes of Jenkins et al in a sealing manner, since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox et al, and to further introduce drugs to the site, since this can prevent or reduce an inflammatory response, among other things, as taught by Ryan et al, thus producing a method such as claimed.

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al in combination with Cox et al and Ryan et al as applied to claim 28 above, and further in combination with Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device. It would have been obvious to the artisan of ordinary skill to employ the balloons of Kalloo et al in the combined method of Jenkins et al in combination with Cox et al and Ryan et al, since this would enable the stabilization thereof with respect to e.g. the septal wall, and would further provide sealing engagement for which balloons are notorious in the art, official notice of which is hereby taken, thus producing a method such as claimed.

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Applicant's arguments with respect to claims 28-35 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is 571-272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 a.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on Monday, Tuesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "David M. Shay", with a stylized, cursive script.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330